SUMMARY OF EXAMINER INTERVIEW

Applicants would like to thank the Examiner Lubin for granting an interview on March 18, 2010. During the interview, the Examiner discussed 35 U.S.C. § 101 concerns regarding claims 7, 11 and 18 and 35 U.S.C. § 103 concerns regarding claims 1, 7, 11 and 18. Differences between the claimed invention and the cited art, namely U.S. Publication No. 6,092,102 to Wagner were discussed. Additionally, proposed amendments to independent claims 1, 7, 11 and 18 were discussed.

REMARKS

The Office Action mailed November 27, 2009 has been received and reviewed. Each of claims 1, 2, 5, 7, 8 and 11-21 stands rejected. Claims 1, 7, 11, and 18 have been amended herein. Support for the present amendments can be found in the Specification at paragraphs [0022], [0025], and [0027]. Care has been exercised to introduce no new subject matter. Reconsideration of the above-identified application in view of the above amendments and the following remarks is respectfully requested.

Rejections based on 35 U.S.C. § 101

Claims 7, 8 and 11-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed towards non-statutory subject matter. Independent claim 7 has been amended to more clearly recite that at least the steps of, accessing a laboratory information system store, analyzing a clinical laboratory order, identifying a clinical laboratory result requiring communication and communicating said laboratory result, are completed by one or more computing device. As such, claim 7 is tied to a particular machine: a computing device.

Applicants also submits that independent claim 11 has been amended to more clearly recite that at least the steps of, identifying a clinical laboratory result requiring communication and automatically generating a communication of said laboratory result, are completed by one or more computing device. As such, claim 11 is tied to a particular machine: a computing device.

Applicants also submits that independent claim 18 has been amended to more clearly recite that at least the steps of, posting clinical laboratory results to the electronic medical record data store, selectively identifying a clinical laboratory result requiring communication and

automatically generating a communication of said laboratory result, are completed by one or more computing device. As such, claim 18 is tied to a particular machine: a computing device.

Accordingly, Applicants respectfully submits that amended claims 7, 11 and 18 are directed to statutory subject matter and respectfully requests withdrawal of the 35 U.S.C. § 101 rejection thereof. Claims 8, 12-17 and 19-21 depend, either directly or indirectly, from independent claims 7, 11 or 18 respectively. As such, Applicants respectfully submits that claims 8, 12-17 and 19-21 are directed to statutory subject matter for at least the reason of their dependence on independent claims 7, 11, and 18. Applicants request withdrawal of the 35 U.S.C. § 101 rejection of claims 8, 12-17 and 19-21.

Rejections based on 35 U.S.C. § 103

Title 35 U.S.C. 103(a) declares that a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." In *Graham v. John Deere,* the Supreme Court counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1 (1966).

"In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." MPEP § 2141.02(I) (emphasis in original) (citing *StratoFlex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983)). "All words in a claim must be considered in judging the

patentability of that claim against the prior art." MPEP § 2143.03 (quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (C.C.P.A. 1970)). Moreover, if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. MPEP § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)).

"The examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness . . . . To reach a proper determination of obviousness, the examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made. In view of all factual information, the examiner must then determine whether the claimed invention 'as a whole' would have been obvious at that time to that person. *Id* (emphasis added). Knowledge of applicant's disclosure must be put aside in reaching this determination . . . . [I]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." MPEP § 2142.

"The key to supporting any rejection under 35 U.S.C. 103 is the **clear articulation of the reason(s)** why the claimed invention would have been obvious." MPEP § 2142 citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S. 2007) (emphasis added), which notes that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. Moreover, the Federal Circuit has stated that "'rejections on obviousness **cannot be sustained with mere conclusory statements**; instead, there must be some **articulated reasoning** with some rational underpinning to support the legal conclusion of obviousness.'" MPEP § 2142 (emphasis added) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). See also *KSR*, 127 S. Ct. at 1741 (quoting Federal Circuit statement with approval).

Claims 1, 2, 5, 7, 8 and 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner (U.S. Publication No. 6,092,102, hereinafter Wagner) in view of Menschik et al. (U.S. Publication No. 2004/0034550, hereinafter Menschik) further in view of Zakim (U.S. Patent No. 7,379,885, hereinafter Zakim). As the asserted combination of references fails to teach or suggest each and every of the limitations set forth in the rejected claims, Applicants respectfully traverse these rejections, as hereinafter set forth.

Independent claim 1, as amended herein, is generally directed to a computerized system for managing the communication of a laboratory result to a person placing a laboratory order. The system includes: a laboratory information system data store storing clinical laboratory results for clinical laboratory orders; an electronic medical record data store storing clinical event information; a results posting module communicating with the laboratory information system data store and electronic medical record data store, the results posting module configured to publish clinical laboratory results from the laboratory information system data store to the electronic medical data store, wherein the results posting module publishes the clinical laboratory results directly from the laboratory information system data store to the electronic medical records data store; an order module for receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results of the laboratory order, wherein the at least two conditions includes a priority level of laboratory order and a normality of the clinical laboratory results associated with the laboratory order; and a callback module for selectively identifying a clinical laboratory result posted in the electronic medical record data store and for requiring a communication directly from the electronic medical record data store to the person placing the laboratory order for the selected clinical laboratory result, wherein the callback module selectively identifies the clinical laboratory result requiring

communication based on, a comparison of the laboratory result and a clinical range relevant to the laboratory result, and information about the clinical laboratory order received from the order module.

Amended independent claim 7 is directed toward a computer-implemented method of managing the communication of a laboratory result to a person placing a laboratory order. The method includes: receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results associated with the laboratory order, wherein the at least two conditions include a priority level of laboratory order and a normality of the clinical laboratory results; accessing utilizing one or more computing device, a laboratory information system data store containing a plurality of laboratory results; posting the laboratory results from the laboratory information system data store to an electronic medical records data store; analyzing utilizing one or more computing device, the clinical laboratory order for the clinical laboratory results; comparing the laboratory result posted in the electronic medical record data store to a clinical range relevant to the laboratory result; selectively identifying, utilizing one or more computing device, a clinical laboratory result requiring a communication to the person placing the laboratory order; and communicating the clinical laboratory result requiring communication directly from the electronic medical record data store to the person placing the laboratory order utilizing one or more computing device.

Applicants respectfully submit that none of the references, taken singularly or in combination, teach or suggest the combination of a system for managing the communication of a laboratory results to a person placing a laboratory order involving receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results associated with the laboratory order, where the at least two conditions

include a priority level of laboratory order and a normality of the clinical laboratory results associated with the laboratory order.

In contrast to the inventions of claims 1 and 7, the Wagner reference discloses a system and method for notifying users about information or events of an enterprise by communicating a message to a user via a user preferred communication channel. *See generally, Wagner* at col. 3, lines 31-34. In Wagner an information processing system receives information from a data generation sub-system such as a laboratory information systems and sends the information to a clinical event monitor which analyzes the information and creates an alert "including message data structure and delivery instructions" and sends the alert to a notifier function. *Id.* at col. 7, lines 37-48. The notifier function of Wagner the selects the communication channel preferred by a user to communicate the message from the event monitor. *Id.* at 6, lines 40-44.

It is respectfully submitted that Wagner fails to disclose receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results associated with the laboratory order, where the at least two conditions include a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order. Instead, in Wagner an event monitor analyzes laboratory information received from a laboratory information system and generates a message containing "an interpretation of the result" and delivery instructions for the message, the delivery instructions being based on the preferred communication channel selected by the user. *Id.* at 7, lines 48-51. The event monitor of Wagner looks for "specific patterns in the data being passed to it from a database" and interprets the results based on rules maintained in a local working memory. *Id.* at 8, lines 35-40. Nowhere does the Wagner reference disclose receiving instructions regarding the conditions for automatically notifying a clinician of the results

associated with a laboratory order *directly from the clinician*. Furthermore, nowhere does Wagner disclose the conditions received from the clinician including a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order. Applicants respectfully point out that merely sending an interpretation of a laboratory result does not equate to determining whether a laboratory result stored in a patients electronic medical records requires communication to a clinician based on conditions received directly from the clinician and communicating the actual laboratory results to the clinician. As such, Wagner fails to disclose a system for managing the communication of a laboratory result to a person placing a laboratory order in the same manner as the invention of claims 1 and 7.

The Menschik reference is directed to a method for creating a secure, centrally-mediated, peer-to-peer network of healthcare providers requiring no pre-existing affiliations of each other. *See Menschik* at ¶ [0027]. It is respectfully submitted that Menschik fails to cure the deficiencies of Wagner. The Menschik reference does not teach, selectively identifying a clinical laboratory result posted in the electronic medical record data store and communicating the identified laboratory result directly from the electronic medical record data store to the person placing the laboratory order for the selected clinical laboratory result as described in the invention of claims 1 and 7. Furthermore, Menschick does not disclose receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results associated with the laboratory order, where the at least two conditions include a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order.

Menschik merely discusses an electronic medical record system that permits healthcare providers to enter clinical observations and retrieve patient notes and charts, while a

clinical data repository provides storage for patient records. *Id.* at ¶ [0092]. The invention of claims 1 and 7 includes communicating a selected clinical laboratory result directly from the electronic medical record data store to the person placing the laboratory order the selection process based on conditions for production received directly from the person placing the laboratory order. Nowhere does Menschik disclose receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results associated with the laboratory order, where the at least two conditions include a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order. The absence of a description in Menschik for receiving *directly* from a clinician conditions for automatically notifying the person of the results associated with the laboratory order prevents Menschik from disclosing a system for managing the communication of a laboratory result to a person placing a laboratory order in the same manner as the invention of claims 1 and 7.

The Zakim reference is directed to a system by which physicians and patients interact to construct medical histories of each patient and then analyze the medical histories of other system subscribers. *See generally, Zakim* at col. 11, lines 20-35. It is respectfully submitted that Zakim fails to cure the deficiencies of Wagner and Menschik. Zakim does not disclose receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results associated with the laboratory order, where the at least two conditions include a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order. Zakim recites notifying a physician whenever a significant medical fact is added by a laboratory to the patient's medical history database. *Id.* at col. 30, lines 17-21.

The invention of claims 1 and 7 includes communicating a selected clinical laboratory result directly from the electronic medical record data store to the person placing the laboratory order, the selection process based on conditions for production received directly from the person placing the laboratory order. Nowhere does Zakim disclose the conditions received directly from the clinician including, a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order. The absence of a description in Zakim for receiving *directly* from a clinician conditions for automatically notifying the person of the results associated with the laboratory order prevents Zakim from disclosing a system for managing the communication of a laboratory result to a person placing a laboratory order in the same manner as the invention of claims 1 and 7.

As the Wagner reference in view of the Menschik and Zakim references fails to teach or suggest all the limitations of the independent claims 1 and 7, a *prima facie* case of obviousness has not been made for independent claims 1 and 7 with respect to these references. Accordingly, Applicants respectfully requests withdrawal of the 35 U.S.C. § 103(a) rejection of these claims.

Claims 2-6, and 8-10 depend respectively from independent claims 1 and 7. As such, Applicants respectfully submit that claims 2-10 are patentable over the Wagner, Menschik and Zakim references for at least the above reasons.

Independent claim 11, as amended herein, is directed to a computer-implemented method for communicating a laboratory result to a person placing a laboratory order. The method includes: accessing a data store containing a plurality of clinical laboratory results; accessing an electronic medical record data store containing clinical event information; posting the plurality of clinical laboratory results to the electronic medical record data store; receiving

directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results of the laboratory order, wherein the at least two conditions includes a priority level of laboratory order and a normalcy of the clinical laboratory results associated with the laboratory order; utilizing one or more computing device, selectively identifying directly from the electronic medical record data store a clinical laboratory result requiring communication to the person placing the laboratory order for the selected clinical laboratory result based on, a comparison of the laboratory result and a clinical range relevant to the laboratory result, and information about the clinical laboratory order; identifying a first preferred notification method for the selected laboratory result; and automatically generating, utilizing one or more computing device, a communication of the selected laboratory result by the first preferred method directly from the electronic medical record data store to the person placing the laboratory order.

As amended herein, independent claim 18 is directed to a computer-implemented method for communicating a laboratory result to a person placing a laboratory order. The method includes: accessing a data store containing a plurality of clinical laboratory results; accessing an electronic medical record data store containing clinical event information; posting utilizing one or more computing device, the plurality of clinical laboratory results to the electronic medical record data store; receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results of the laboratory order, wherein the at least two conditions includes a priority level of laboratory order and a normalcy of the clinical laboratory results associated with the laboratory order; utilizing one or more computing device, selectively identifying directly from the electronic medical record data store a clinical laboratory result requiring communication to the person placing the

laboratory order for the selected clinical laboratory result based on, a comparison of the laboratory result and a clinical range relevant to the laboratory result, and information about the clinical laboratory order; identifying a first preferred notification method for the selected laboratory result from a plurality of notification methods; identifying a number of conditions for the preferred method; and if the conditions are satisfied, automatically generating utilizing one or more computing device, a communication of the laboratory result by the first preferred method directly from the electronic medical record data store to the person placing the laboratory order.

In contrast to the inventions of claims 11 and 18, the Wagner reference discloses a system and method for notifying users about information or events of an enterprise by incorporating user preferences for communication channels to communicate a message as a function of the message, such as based on the message type. *See generally, Wagner* at col. 3, lines 31-34. In Wagner an information processing system receives information from a data generation sub-system such as a laboratory information systems and sends the information to a clinical event monitor which analyzes the information and creates an alert "including message data structure and delivery instructions" and sends the alert to a notifier function *Id.* at col. 7, lines 37-48. The notifier function of Wagner the selects the communication channel preferred by a user to communicate the message from the event monitor. *Id.* at 6, lines 40-44.

It is respectfully submitted that Wagner fails to disclose receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results of the laboratory order, wherein the at least two conditions includes a priority level of laboratory order and a normalcy of the clinical laboratory results associated with the laboratory order as described in claims 11 and 18. Instead, in Wagner, an event monitor analyzes laboratory information received from a laboratory information system and generates a

message containing "an interpretation of the result" and delivery instructions for the message. *Id.* at 7, lines 48-51. The event monitor of Wagner looks for "specific patterns in the data being passed to it from a database" and interprets the results based on rules maintained in a local working memory. *Id.* at 8, lines 35-40. Nowhere does the Wagner reference disclose receiving instructions regarding the conditions for automatically notifying a clinician of the results associated with a laboratory order *directly from the clinician*. Furthermore, nowhere does Wagner disclose the conditions received from the clinician including a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order. Applicants respectfully point out that merely sending an interpretation of a laboratory result does not equate to determining whether a laboratory result stored in a patients electronic medical records requires communication to a clinician based on conditions received directly from the clinician and communicating the actual laboratory results to the clinician. As such, Wagner fails to disclose a system for managing the communication of a laboratory result to a person placing a laboratory order in the same manner as the invention of claims 11 and 18.

The Menschik reference is directed to a method for creating a secure, centrally-mediated, peer-to-peer network of healthcare providers requiring no pre-existing affiliations of each other. *See Menschik* at ¶ [0027]. It is respectfully submitted that Menschik fails to cure the deficiencies of Wagner. The Menschik reference does not teach, selectively identifying a clinical laboratory result posted in the electronic medical record data store and communicating the identified laboratory result directly from the electronic medical record data store to the person placing the laboratory order for the selected clinical laboratory result as described in the invention of claims 11 and 18. Furthermore, Menschik does not disclose receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the

person of the results associated with the laboratory order, where the at least two conditions include a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order. Menschik merely discusses an electronic medical record system that permits healthcare providers to enter clinical observations and retrieve patient notes and charts, while a clinical data repository provides storage for patient records. *Id.* at ¶ [0092].

The invention of claims 11 and 18 includes communicating a selected clinical laboratory result directly from the electronic medical record data store to the person placing the laboratory order the selection process based on conditions for production received directly from the person placing the laboratory order. Nowhere does Menschik disclose receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results associated with the laboratory order, where the at least two conditions include a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order. The absence of a description in Menschik for receiving *directly* from a clinician conditions for automatically notifying the person of the results associated with the laboratory order prevents Menschik from disclosing a system for managing the communication of a laboratory result to a person placing a laboratory order in the same manner as the invention of claims 11 and 18.

The Zakim reference is directed to a system by which physicians and patients interact to construct medical histories of each patient and then analyze the medical histories of other system subscribers. *See generally, Zakim* at col. 11, lines 20-35. It is respectfully submitted that Zakim fails to cure the deficiencies of Wagner and Menschik. Zakim does not disclose receiving directly from the person requesting a laboratory order at least two conditions for automatically notifying the person of the results associated with the laboratory order, where

the at least two conditions include a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order. Zakim recites notifying a physician whenever a significant medical fact is added by a laboratory to the patient's medical history database. *Id.* at col. 30, lines 17-21.

The invention of claims 11 and 18 includes communicating a selected clinical laboratory result directly from the electronic medical record data store to the person placing the laboratory order, the selection process based on conditions for production received directly from the person placing the laboratory order. Nowhere does Zakim disclose the conditions received directly from the clinician including, a priority level of the laboratory order and a normality of the clinical laboratory results associated with the laboratory order. The absence of a description in Zakim for receiving *directly* from a clinician conditions for automatically notifying the person of the results associated with the laboratory order prevents Zakim from disclosing a system for managing the communication of a laboratory result to a person placing a laboratory order in the same manner as the invention of claims 11 and 18.

As the Wagner reference in view of the Menschik and Zakim references fails to teach or suggest all the limitations of the independent claims 11 and 18, a *prima facie* case of obviousness has not been made for independent claims 11 and 18 with respect to these references. Accordingly, Applicants respectfully requests withdrawal of the 35 U.S.C. § 103(a) rejection of these claims.

Claims 12-17, and 19-21 depend respectively from independent claims 11 and 18. As such, Applicants respectfully submit that claims 12-17, and 19-21 are patentable over the Wagner, Menschik and Zakim reference for at least the above reasons.

CONCLUSION

For at least the reasons stated above, claims 1, 2, 5, 7-8, and 11-21 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or ajthompson@shb.com (such communication via email is herein expressly granted) – to resolve the same. It is believed that no fee is due, however, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112.

REQUEST FOR EXTENSION OF TIME

It is hereby requested that the time period for responding to the outstanding Office Action mailed November 27, 2009, be extended for one month or until March 27, 2009. The Petition fee of $130 is being submitted simultaneously with this paper by way of electronic payment.

In the event it is determined necessary, the Commissioner is hereby authorized to charge any additional fee which may be required, or credit any overpayment, to Deposit Account No. 19-2112.

Respectfully submitted,

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